

Chapter 26

Parenteral Preparations

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OVERVIEW OF UNIQUE CHARACTERISTICS OF PARENTERAL DOSAGE FORMS

Parenteral products are unique from any other type of pharmaceutical dosage form for the following reasons:

- All products must be sterile.
- All products must be free from pyrogenic (endotoxin) contamination.
- Injectable solutions must be free from visible particulate matter. This includes reconstituted sterile powders.
- Products should be isotonic, although strictness of isotonicity depends on the route of administration. Products administered into the cerebrospinal fluid must be isotonic. Ophthalmic products, although not parenteral, must also be isotonic. Products to be administered by bolus injection by routes other than intravenous (IV) should be isotonic, or at least very close to isotonicity. IV infusions must be isotonic.
- All products must be stable, not only chemically and physically like all other dosage forms, but also 'stable' microbiologically (i.e., sterility, freedom from pyrogenic and visible particulate contamination must be maintained throughout the shelf life of the product).
- Products must be compatible, if applicable, with IV diluents, delivery systems, and other drug products co-administered.

Parenteral (Gk, *para* = across, beside the intestine) dosage forms differ from all other drug dosage forms, because they are injected directly into body tissue through the primary protective systems of the human body, the skin, and mucous membranes. They must be exceptionally pure and free from physical, chemical, and biological contaminants. These requirements place a heavy responsibility on the pharmaceutical industry to practice current good manufacturing practices (cGMPs) in the manufacture of parenteral dosage forms and on pharmacists and other health care professionals to practice good aseptic practices (GAPs) in dispensing parenteral dosage forms for administration to patients.

Certain pharmaceutical agents, particularly peptides, proteins, and many chemotherapeutic agents, can only be given parenterally, because they are inactivated in the gastrointestinal tract when given by mouth. Parenterally-administered drugs are relatively unstable and generally highly potent drugs that require strict control of administration to the patient. Due to the advent of biotechnology, parenteral products have grown in number and usage around the world.

This chapter focuses on the unique characteristics of parenteral dosage forms and the basic principles for formulating, packaging, manufacturing, and controlling the quality of these unique products. The references and bibliography at the end of this chapter contain the most up-to-date texts, book chapters, and review papers on parenteral product formulation, manufacture, and quality control.

Chapter 26 Parenteral Preparations Pharmaceutical Press

Anthony S. Fauci



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Pharmaceutical Practice E-Book Arthur J. Winfield, Judith Rees, Ian Smith, 2009-07-21 This comprehensive book covers a wide range of subjects relevant to pharmacy practice including communication skills managing a business quality assurance dispensing calculations packaging storage and labeling of medicines sterilization prescriptions hospital based services techniques and treatments adverse drug reactions pharmacoeconomics and medicines management Features useful appendices on medical abbreviations pharmaceutical Latin terms weights and measures and presentation skills This is a core text for pharmacy practice and dispensing modules of the pharmacy curriculum Covers key exam material for essential review and test preparation Features a user friendly design with clear headings chapter summaries helpful boxes and key points Text restructured with 14 new or radically revised chapters All text revised in light of current pharmaceutical practice New design using two colours *Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals* Tim Sandle, 2025-08-01 Sterility Sterilisation and Sterility Assurance for Pharmaceuticals Technology Validation and Current Regulations Second Edition is an in depth guide to the world of pharmaceutical sterilization This new edition has been updated to reflect the latest standards and regulations ensuring alignment with current practices It explores emerging methods and techniques complemented by new case studies that provide practical examples Readers will gain comprehensive knowledge about sterilization's critical role in healthcare and pharmaceutical manufacturing highlighting the importance of controlling microbial challenges to ensure product safety and patient well being The book discusses sterility sterilization methods such as gamma radiation e beam dry heat steam gas vapor filtration and new techniques like X ray sterilization liquid phase sterilization ultraviolet light supercritical gases and sterilization assurance governance It covers biopharmaceutical manufacturing processes including aseptic filling container and packaging design and cleanroom environments This edition is essential for professionals in pharmaceuticals healthcare and medical device manufacturing providing the knowledge needed to comply with current standards and regulations Includes nine new chapters with many new case studies Offers coverage on the most current standards and regulations Provides full coverage of novel sterilization methods **Remington** David B. Troy, Paul Beringer, 2006 For over 100 years Remington has been the definitive textbook and reference on the science and practice of pharmacy This Twenty First Edition keeps pace with recent changes in the pharmacy curriculum and professional pharmacy practice More than 95 new contributors and 5 new section editors provide fresh perspectives on the field New chapters include pharmacogenomics application of ethical principles to practice dilemmas technology and automation professional communication medication errors re engineering pharmacy practice management of special risk medicines specialization in pharmacy practice disease state management emergency patient care and wound care Purchasers of this textbook are entitled to a new fully indexed Bonus CD ROM affording instant access to the full content of Remington in a convenient and portable format *Handbook of Institutional Pharmacy Practice* Mickey C. Smith, Thomas R.

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